



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
College Park, MD 20740

SEP 29 2004

Stephen M. Paul, Ph.D.
President
Vita Pharmica
6 Morgan
Suite 112
Irving, California 92618

Dear Dr. Paul:

This is in response to your letter of July 22, 2004 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)).

Your letter states that the following statement will be made for the product PressAssure: "[M]aintaining healthy blood pressure."

In the preamble to the January 6, 2000 final rule on structure/function claims (see 65 FR 1000 at 1018), FDA stated that claims about the maintenance of normal cholesterol levels did not necessarily constitute implied disease claims. We stated, however, that because "many people think of cholesterol solely in terms of the negative role of elevated cholesterol in heart disease," in order to avoid implying that the product prevents or treats heart disease, a cholesterol maintenance claim would have to clarify that the product is only for maintenance of cholesterol levels that are already within the normal range. The same principle applies to claims about the control of blood pressure; that is, a claim that does not establish that the claims are about blood pressure that is already within normal limits implies that the product is intended to treat elevated blood pressure (hypertension), which is a disease. Therefore, because the claim you are making for this product represents that the product is intended to affect blood pressure but does not also include a statement about it being intended to affect blood pressure that is already in the normal range, it is an implied disease claim.

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statement that you are making for this product suggests that it is intended to treat, prevent, or mitigate a disease. This claim does not meet the requirements of 21 U.S.C. 343(r)(6). This claim suggests that this product is intended for use as a drug within the meaning of 21 U.S.C. 321(g)(1)(B), and that it is subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, Montrose Metro II, 11919 Rockville Pike, Rockville, Maryland 20855.

975-0163

LET 783

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Please contact us if we may be of further assistance.

Sincerely yours,

A handwritten signature in black ink, appearing to be 'SN' with a long horizontal stroke extending to the right.

Susan J. Walker, M.D.
Director
Division of Dietary Supplement Programs
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-310

FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of
Enforcement, HFC-200

FDA, Los Angeles District Office, Office of Compliance, HFR-PA240



Vita Pharmica

The Best Choice for Your Health™

6 Morgan, Suite 112

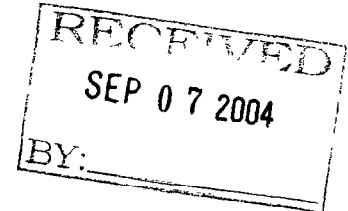
Irvine, CA 92618

Phone 1-888-686-3683 • 949-588-8038 • fax 949-588-8086

July 22, 2004

CERTIFIED MAIL
Return Receipt Requested

Dr. Robert J. Moore
Branch Chief, Compliance & Enforcement Branch
Office of Nutrition Products, Labeling and Dietary Supplements
FOOD & DRUG ADMINISTRATION (HFS-800)
5100 Paint Brush Parkway
College Park, Maryland 20740



Dear Dr. Moore:

This letter is submitted pursuant to Section 406 (r)(6) of the Federal Food, Drug, and Cosmetic Act for the purpose of notifying the Agency of statements being made in connection with the marketing of dietary supplements which are being distributed by this company.

The text of the statement that is being made is as follows:

Advanced Formula for Maintaining Healthy Blood Pressure

The name of the Product is as follows:

PressAssure, 120 Tablets

The dietary ingredients for which this statement is being made are:

Baikal skullcap root, *Cassia tora* L. seed, cnidium rhizome, white peony radix and turmeric rhizome.

Below the claim on the principal display panel is a ruled DSHEA disclaimer, "This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease."

As required, enclosed are two additional copies of this notification.

The signee certifies that the information contained in this notice is complete and accurate, and that Vitapharmica has substantiation that the statement being made is truthful and not misleading.

Sincerely,

Dr. Stephen M. Paul, PhD
President
Vitapharmica, Inc.

Enclosures

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